LH release by the pituitary, the inhibitive effect of circulating estradiol in obese and non-obese men

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To study whether higher estradiol levels in obese men are responisble for the lower testosterone levels also found in these men

Ethical review	Approved WMO
Status	Pending
Health condition type	Endocrine disorders of gonadal function
Study type	Interventional

Summary

ID

NL-OMON31039

Source
ToetsingOnline

Brief title
obE2se study

Condition

- Endocrine disorders of gonadal function

Synonym
obesity

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: researchbudget afdeling

Intervention

Keyword: obesity male LH testosterone

Outcome measures

Primary outcome

before every change of estradiol dose and at the end of the study blood is

drawn for determination of estradiol, testosterone, sex hormone binding

globulin and LH

Secondary outcome

non applicable

Study description

Background summary

from our previously conducted studies it appeared that circulating estradiol has a strong and inhibitive effect on gonadotropin release by the male pituitary. Obese men have higher mean plasma estradiollevels and lower mean plasma testosterone levels compared to non-obese men.

Study objective

To study whether higher estradiol levels in obese men are responisble for the lower testosterone levels also found in these men

Study design

open lable intervention study

Intervention

the endogenoud estradiolsynthesis is inhibited by letrozole tablest 2,5 mg daily. Estradiol levels are varied by application of estradiol patches in different doses. The effect of varying estradiol levels on the levels of LH and testosterone are observed and compared with results from a similar study in non-obese men.

Study burden and risks

duration of the study is 28 days comprising 5 visits (75 minutes in total), 5 venepunctures (35 ml in total). Intake of letrozole 2,5 mg tablets once daily for 28 days. Application of estradiol patches 2 times per week for a total of 3 weeks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

male, BMI > 35 kg/m2, age < 40 years

Exclusion criteria

history of hypogonadism, pituitary disease, venous thrombosis. Use of testosterone, aldactone, finasteride, glucocorticoids. LH > 8 IU/L

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL19638.029.07